CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

Article 1.4.1.

Introduction and objectives

1) In general, *surveillance* is aimed at demonstrating the absence of *disease* or *infection*, determining the presence or distribution of *disease* or *infection* or detecting as early as possible exotic or *emerging diseases*. The type of *surveillance* applied depends on the outputs needed to support decision-making. The following recommendations may be applied to all *diseases* or *infections* and all susceptible species (including *wildlife*). The general recommendations in this chapter may be refined by the specific approaches described in the *disease* chapters. Where detailed *disease* or *infection*-specific information is not available, suitable approaches should be based on the recommendations in this chapter.

2) Animal health *surveillance* is also a tool to monitor disease trends, to facilitate the control of *disease* or *infection*, to provide data for use in *risk analysis*, for animal or public health purposes, and to substantiate the rationale for sanitary measures. Both domestic *animals* and *wildlife* are susceptible to certain *diseases* or *infections*. However, the presence of a *disease* or *infection* in *wildlife* does not mean it is necessarily present in domestic *animals* in the same country or *zone* or vice versa. *Wildlife* may be included in a *surveillance* system because they can serve as reservoirs of *infection* and as indicators of *disease risk* to humans and domestic animals. *Surveillance* in *wildlife* presents challenges that may differ significantly from those in *surveillance* in domestic *animals*.

3) Prerequisites to enable a Member Country to provide information for the evaluation of its animal health status are:
   a) that the Member Country complies with the provisions of Chapter 3.1.;
   b) that, where possible, *surveillance* data be complemented by other sources of information, such as scientific publications, research data, documented field observations and other non-survey data;
   c) that transparency in the planning and execution of *surveillance* activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1.

4) The objectives of this chapter are to:
   a) provide guidance to the type of outputs that a *surveillance* system should generate;
   b) provide recommendations to assess the quality of *surveillance* systems.

Article 1.4.2.

Definitions

The following definitions apply for the purposes of this chapter:

Bias: means a tendency of an estimate to deviate in one direction from a true value.

Confidence: means the probability that the type of *surveillance* applied would detect the presence of *infection* if the population were infected and is equivalent to the sensitivity of the *surveillance*. Confidence depends on, among other parameters, the assumed prevalence of *infection*.

Probability sampling: means a sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

Sample: means the group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide *surveillance* information.

Sampling unit: means the unit that is sampled, either in a random survey or in non-random *surveillance*. This may be an individual *animal* or a group of *animals*, such as an *epidemiological unit*. Together, they comprise the sampling frame.

Sensitivity: means the proportion of truly positive units that are correctly identified as positive by a test.

Specificity: means the proportion of truly negative units that are correctly identified as negative by a test.

Study population: means the population from which *surveillance* data are derived. This may be the same as the target population or a subset of it.

Surveillance system: means a method of *surveillance* that may involve one or more component activities that generates information on the health or disease status of animal populations.

Survey: means an investigation in which information is collected systematically usually carried out on a sample of a defined population group, within a defined time period.

Target population: means the population about which conclusions are to be inferred.

Test: means a procedure used to classify a unit as either positive, negative or suspect with respect to a *disease* or an *infection*.

Test system: means a combination of multiple tests and rules of interpretation which are used for the same purpose as a test.

Article 1.4.3.

Principles of surveillance

1. Types of surveillance
   a) *Surveillance* may be based on many different data sources and can be classified in a number of ways, including:
      i) the means by which data are collected (active versus passive *surveillance*);
      ii) the disease focus (pathogen-specific versus general *surveillance*); and
      iii) the way in which units for observation are selected (structured surveys versus non-random data sources).
   b) In this chapter, *surveillance* activities are classified as being based on:
      EITHER
      i) structured population-based surveys, such as:
         – systematic sampling at *slaughter*;
         – random surveys;
         – surveys for *infection* in clinically normal *animals*, including *wildlife*;
      OR
      ii) structured non-random *surveillance* activities, such as:
         – *disease* reporting or notifications;
         – control programmes or health schemes;
         – targeted testing or screening;
         – ante-mortem and post-mortem inspections;
         – laboratory investigation records;
         – biological specimen banks;
         – sentinel units;
         – field observations;
         – farm production records;
         – *wildlife* disease data.
   c) In addition, *surveillance* data should be supported by related information, such as:
      i) data on the epidemiology of the *disease* or *infection*, including environmental, host population distribution, and climatic information;
      ii) data on animal movements, including transhumance and natural *wildlife* migrations;
      iii) trading patterns for *animals* and animal products;
      iv) national animal health regulations, including information on compliance with them and their effectiveness;
      v) history of imports of potentially infected material;
      vi) biosecurity measures in place; and

vii) the likelihood and consequence of *disease* or *infection* introduction.

d) The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

2. Critical elements

In assessing the quality of a *surveillance* system, the following critical elements need to be addressed over and above quality of *Veterinary Services* (Chapter 3.1.).

a) Populations

Ideally, *surveillance* should be carried out in such a way as to take into account all animal species susceptible to the *infection* in a country, *zone* or *compartment*. The *surveillance* activity may cover all individuals in the population or part of them. When *surveillance* is conducted only on a *subpopulation*, care should be taken regarding the inferences made from the results.

Definitions of appropriate populations should be based on the specific recommendations of the disease chapters of the *Terrestrial Code*.

b) Time frame (or temporal values of surveillance data)

Surveillance should be carried out at a frequency that reflects the biology of the *infection* and the *risks* of its introduction.

c) Epidemiological unit

The relevant *epidemiological unit(s)* for the *surveillance* system should be defined to ensure that it is appropriate to meet the objectives of *surveillance*. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, *vectors*, immune status, genetic resistance and age, sex, and other host criteria.

d) Clustering

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of infected *animals* within a *herd*, a cluster of pens in a building, or a cluster of farms in a *compartment*). Clustering should be taken into account in the design of *surveillance* activities and the statistical analysis of *surveillance* data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection*.

e) Case definition

Where one exists, the case definition in the specific chapter of the *Terrestrial Code* should be used. If the *Terrestrial Code* does not give a case definition, a case should be defined using clear criteria for each *disease* or *infection* under *surveillance*. For *wildlife disease* or *infection surveillance*, it is essential to correctly identify and report host animal taxonomy (including genus and species).

f) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational level to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of *surveillance* data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate different host species, pathogens, production systems and *surveillance* systems, and types and amounts of data and information available.

The methodology used should be based on the best information available. It should also be in accordance with this chapter, fully documented and supported by reference to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

g) Testing

Surveillance involves the detection of *disease* or *infection* according to appropriate case definitions and based on the results of one or more tests for evidence of *infection* or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity, its specificity and predictive values. Imperfect sensitivity or specificity will have an impact on the

conclusions from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

The sensitivity and specificity values of the tests used should be specified for each species in which they may be used, and the method used to estimate these values should be documented. Alternatively, where sensitivity or specificity values of a particular test are specified in the *Terrestrial Manual*, these may be used as a guide.

Samples from a number of *animals* or units may be pooled and subjected to a testing protocol. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

h) Quality assurance

Surveillance systems should incorporate the principles of quality assurance. They should be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

i) Validation

Results from animal health *surveillance* systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

j) Data collection and management

The success of a *surveillance* system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis is critical. Factors influencing the quality of collected data include:

– the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location; this requires effective collaboration among all stakeholders, such as governmental or non-governmental organisations, and others, particularly for data involving *wildlife*;

– the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;

– maintenance of disaggregated data rather than the compilation of summary data;

– minimisation of transcription errors during data processing and communication.

Article 1.4.4.

Structured population-based surveys

In addition to the principles discussed in Article 1.4.3., the following should be considered when planning, implementing and analysing surveys.

1. Types of surveys

Surveys may be conducted on the entire target population (i.e. a census) or on a sample. A sample may be selected in either of two ways:

a) non-probability based sampling methods, such as:

i) convenience;

ii) expert choice;

iii) quota;

b) probability based sampling methods, such as:

i) simple random selection;

ii) cluster sampling;

iii) stratified sampling;

iv) systematic sampling.

Periodic or repeated surveys conducted in order to document *disease* freedom should be conducted using probability based sampling methods so that data from the study population can be extrapolated to the target population in a statistically valid manner.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be given to any biases that may be inherent in the survey design.

2. Survey design

The population of *epidemiological units* should first be clearly defined; hereafter appropriate sampling units should be defined for each stage, depending on the design of the survey.

The design of the survey will depend on the size, structure and degree of understanding of the population being studied, the epidemiology of the *infection* and the resources available.

Data on *wildlife* population size often do not exist. However, they should be determined to the extent possible before the survey is designed. The expertise of *wildlife* biologists may be sought in the gathering and interpretation of such population data. Historical population data should be updated since these may not reflect current populations.

3. Sampling

The objective of sampling from a population is to select a subset of units that is representative of the population of interest with respect to the objective of the study. Sampling should provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems.

Specimens of *wildlife* may be available from sources such as hunters and trappers, road-kills, *wild animal meat* markets, sanitary inspection of hunted *animals*, morbidity-mortality observations by the general public, *wildlife* rehabilitation centres, *wildlife* biologists and *wildlife* agency field personnel, farmers, and other landholders, naturalists and conservationists. *Wildlife* data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

4. Sampling methods

When selecting *epidemiological units* from within a population, probability sampling, such as simple random selection, should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

In any case, the sampling method used at all stages should be fully documented.

5. Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. *infection*) or to estimate a parameter (e.g. the prevalence of *infection*). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Article 1.4.5.

Structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys.

1. Common non-random surveillance sources

A wide variety of non-random *surveillance* sources may be available. These vary in their primary purpose and the type of *surveillance* information they are able to provide. Some *surveillance* systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from *infection*. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data, such as disease reporting systems, sentinel sites and testing schemes.

a) Disease reporting or notification systems

Data derived from *disease* reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for *risk analysis*, or for early detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on

laboratory confirmation of suspect clinical *cases* should use tests that have a high specificity. Reports should be released by the *laboratory* in a timely manner, with the amount of time from *disease* detection to report generation minimized (to hours in the case of introduction of a foreign animal disease).

Whenever the responsibility for disease notification falls outside the scope of the *Veterinary Authority*, for example in some countries for *diseases* in *wildlife*, effective communication and data sharing should be established with the relevant authorities to ensure comprehensive and timely disease reporting.

b) Control programmes and health schemes

Animal *disease* control programmes or health schemes, while focusing on the control or eradication of specific *diseases*, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured *surveillance*.

c) Targeted testing and screening

This may involve testing targeted to selected sections of the population (subpopulations), in which *disease* is more likely to be introduced or found. Examples include testing culled and dead *animals*, swill fed *animals*, those exhibiting clinical signs, *animals* located in a defined geographic area and specific age or commodity group.

d) Ante-mortem and post-mortem inspections

Inspections of *animals* at *slaughterhouses* may provide valuable *surveillance* data. The sensitivity and specificity of *slaughterhouse* inspection for detecting the presence of specified *diseases* should be pre-determined for the inspection system in place. The accuracy of the inspection system will be influenced by:

i) the training, experience and number of the inspection staff;

ii) the involvement of the *Competent Authority* in the supervision of ante-mortem and post-mortem inspections;

iii) the quality of construction of the *slaughterhouse*, speed of the slaughter chain, lighting quality, etc.; and

iv) staff morale and motivation for efficient performance.

Slaughterhouse inspections are likely to provide good coverage for particular age groups and geographical areas only. *Slaughterhouse surveillance* data are subject to biases in relation to target populations (e.g. only *animals* of a particular class and age are likely to be slaughtered for human consumption in significant numbers). Such biases need to be recognised when analysing *surveillance* data.

For traceback and analysis of spatial and *herd*-level coverage, there should be, if possible, an effective identification system that relates *animals* in the *slaughterhouse* to their locality of origin.

e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful *surveillance* information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector *laboratories*. Valid analysis of data from different *laboratories* depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. As with *abattoir* inspections, there needs to be a mechanism to relate specimens to the farm of origin.

f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection*, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

g) Sentinel units

Sentinel units or sites involve the identification and regular testing of one or more of *animals* of known health or immune status in a specified geographical location to detect the occurrence of *disease* or *infection* (usually serologically). They are particularly useful for *surveillance* for *diseases* or *infections* which have a strong spatial component, such as *vector*-borne *diseases* or *infections*. Sentinel units provide the opportunity to target *surveillance* depending on the likelihood of *infection* (related to *vector* habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from *infection*, or provide data on prevalence and incidence as well as the distribution of *disease* or *infection*.

h) Field observations

Clinical observations of *animals* in the field are an important source of *surveillance* data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is important. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of *disease* or *infection* at the *herd* or *flock* level. In general, the sensitivity of this approach may be quite high (depending on the *disease*), but the specificity is often quite low.

j) Wildlife data

Specimens from *wildlife* for *disease* or *infection surveillance* may be available from sources such as hunters and trappers, road-kills, *wild animal meat* markets, sanitary inspection of hunted *animals*, morbidity and mortality observations by the general public, *wildlife* rehabilitation centres, *wildlife* biologists and *wildlife* agency field personnel, farmers and other landholders, naturalists and conservationists. *Wildlife* data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

2. Critical elements for structured non-random surveillance

There are a number of critical factors which should be taken into account when using structured non-random *surveillance* data. These include coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. *Surveillance* data from non-random sources can, however, be a cost-efficient method of early detection, and may increase the level of confidence or detect a lower level of prevalence compared to random sampling surveys.

3. Analytical methodologies

Different scientifically valid methodologies may be used for the analysis of non-random *surveillance* data. Where no data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

4. Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented, including references to published material.

Surveillance information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. For instance, repeated annual surveys may be analysed to provide a cumulative level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in a shorter period of time.

Analysis of *surveillance* information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

Article 1.4.6.

Surveillance to demonstrate freedom from disease or infection

1. Requirements to declare a country or a zone free from disease or infection without pathogen specific surveillance

This article provides general principles for declaring a country or a *zone* free from *disease* or *infection* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this article are based on Article 1.4.3. and the following premises:

– in the absence of *disease* and *vaccination*, the animal population would become susceptible over a period of time;

– the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible *animals*;

– competent and effective *Veterinary Services* will be able to investigate, diagnose and report *disease*, if present;

– *disease* or *infection* can affect both domestic *animals* and *wildlife*;

– the absence of *disease* or *infection* over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by a Member Country.

a) Historically free

Unless otherwise specified in the relevant *disease* chapter, a country or *zone* may be recognised as free from *infection* without formally applying a pathogen-specific *surveillance* programme when:

i) there has never been occurrence of *disease*, or

ii) eradication has been achieved or the *disease* or *infection* has ceased to occur for at least 25 years,

provided that for at least the past 10 years:

iii) the *disease* has been a *notifiable disease*;

iv) an early detection system has been in place for all relevant species;

v) measures to prevent *disease* or *infection* introduction have been in place; no *vaccination* against the *disease* has been carried out unless otherwise provided for in the *Terrestrial Code*;

vi) *infection* is not known to be established in *wildlife* within the country or *zone*. A country or *zone* cannot apply for historical freedom if there is any evidence of *infection* in *wildlife*.

b) Last occurrence within the previous 25 years

Countries or *zones* that have achieved eradication (or in which the *disease* or *infection* has ceased to occur) within the previous 25 years, should follow the pathogen-specific *surveillance* requirements in the *Terrestrial Code* if they exist. In the absence of specific requirements, countries should follow the general recommendations on *surveillance* outlined in this chapter provided that for at least the past 10 years:

i) the *disease* has been a *notifiable disease*;

ii) an early detection system has been in place;

iii) measures to prevent the introduction of the *disease* or *infection* introduction have been in place;

iv) no *vaccination* against the *disease* has been carried out unless otherwise provided for in the *Terrestrial Code*;

v) *infection* is not known to be established in *wildlife* within the country or *zone*. A country or *zone* cannot apply for recognition of freedom if there is any evidence of *infection* in *wildlife*.

2. Recommendations for the discontinuation of pathogen-specific screening after recognition of freedom from infection

A country, *zone* or *compartment* that has been recognised as free from *infection* following the provisions of the *Terrestrial Code* may discontinue pathogen-specific screening while maintaining the infection-free status provided that:

a) the *disease* is a *notifiable disease*;

b) an early detection system is in place;

c) measures to prevent the introduction of the *disease* or *infection* are in place;

d) *vaccination* against the *disease* is not applied;

e) *infection* is known not to be established in *wildlife*. It can be difficult to collect sufficient epidemiological data to prove absence of *disease* or *infection* in *wild animal* populations. In such circumstances, a range of supporting evidence should be used to make this assessment.

3. Self declaration of freedom from disease or infection

A Member Country may make a self declaration according to Chapter 1.6. that its entire territory, a *zone* or a *compartment* is free from a *listed disease*, based on the implementation of the provisions of the *Terrestrial Code* and the *Terrestrial Manual*. The *Veterinary Authority* may wish to transmit this information to the OIE *Headquarters*, which may publish the information.

4. International recognition of disease or infection free status

For *diseases* for which procedures exist whereby the OIE can officially recognise the existence of a *disease* or *infection* free country or *zone*, a Member Country wishing to apply for recognition of this status should, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country or *zone* concerned. Such documentation should be presented according to the recommendations prescribed by the OIE for the appropriate animal *diseases*.

5. Demonstration of freedom from infection

A *surveillance* system to demonstrate freedom from *infection* should meet the following requirements in addition to the general requirements outlined in Article 1.4.3.

Freedom from *infection* implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *infection*. Therefore, demonstrating freedom from *infection* involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Member Countries) that *infection* with a specified pathogen, if present, is present in less than a specified proportion of the population.

However, finding evidence of *infection* at any prevalence in the target population automatically invalidates any freedom from *infection* claim unless otherwise stated in the relevant *disease* chapter. The implications for the status of domestic *animals* of *disease* or *infection* present in *wildlife* in the same country or *zone* should be assessed in each situation, as indicated in the relevant chapter on each *disease* in the *Terrestrial Code*.

Evidence from targeted, random or non-random data sources, as stated before, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

Article 1.4.7.

Surveillance for distribution and occurrence of infection

Surveillance to determine the distribution and occurrence of *infection*, *disease* or of other relevant health-related events is used to assess progress and aid in decision making in the control or eradication of selected *diseases* or *infections*. It also has relevance for the international movement of *animals* and products.

In contrast to *surveillance* to demonstrate freedom from *infection*, *surveillance* used to assess progress in control or eradication of selected *diseases* or *infections* is usually designed to collect data about a number of variables such as:

1) prevalence or incidence of *infection*;
2) morbidity and mortality rates;
3) frequency of *disease or infection risk* factors and their quantification;
4) frequency distribution of *herd* sizes or the sizes of other *epidemiological units*;
5) frequency distribution of antibody titres;
6) proportion of immunised *animals* after a *vaccination* campaign;
7) frequency distribution of the number of days elapsing between suspicion of *infection* and *laboratory* confirmation of the diagnosis and the adoption of control measures;
8) farm production records;
9) role of *wildlife* in maintenance or transmission of the *infection*.